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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/672,685 | 09/26/2003 | Nora Sarvetnick | 18427-001CON2 | 9241 |
| 7590 | 08/14/2006 | | EXAMINER | |
| Ivor R. Elrifi Mintz Levin One Financial Center Boston, MA 02111 | | | GABEL, GAILENE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1641 | |

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application N . 10/672,685 | Applicant(s) SARVETNICK ET AL. | |
| | Examiner Gailene R. Gabel | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 4-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-6 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2/20/04; 7/19/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1 and 2, filed on June 21, 2006, is acknowledged and has been entered. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 3-6 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Currently, claims 1-6 are pending. Claims 1 and 2 are under examination.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration believes the named inventor or inventors to be the first inventor or inventors of the subject matter which is claimed and for which a patent is sought.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 1 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, i.e. how pure is a substantially pure population of viable pancreatic progenitor cells, ... and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 1 is indefinite in reciting, "able to differentiate" because it fails to recite a positive limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitrani et al. (WO 96/40872).

Mitrani et al. disclose a substantially pure population of viable pancreatic progenitor cells. The progenitor cells are inducible to differentiate into pancreatic islet (β -cells and islet δ cells) and are characterized by their expression of PDX-1 (same as STF-1) (see page 1, lines 21-36, page 2, lines 1-8, page 4, lines 8-12). β -cell subset of the population of cells express and produce (secrete) insulin (see page 21, lines 25-31).

In as far as the limitation that the pancreatic progenitor cells are "able to differentiate into glucose-responsive cells", the recitation of "able to differentiate" is not a positive limitation of the claim; therefore, the viable pancreatic progenitor cells in the claimed invention are not required to differentiate into glucose-responsive cells.

Alternatively, since the viable pancreatic progenitor cells are recited to be characterized by expression of PDX-1 which renders them capable of differentiating into glucose-responsive and insulin-secreting cells, and Mitrani specifically taught that the disclosed viable pancreatic progenitor cells express PDX-1 and produce or secrete insulin, it is determined that Mitrani inherently anticipates the claimed invention because production or secretion of insulin of the viable pancreatic progenitor cells is a result effected by a response of the same cells to the presence or increase in glucose levels. Hence, the viable pancreatic progenitor cells of Mitrani are deemed to be glucose-responsive cells.

5. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being inherently anticipated by Habener et al. (US Patent 5,858,973).

Habener et al. disclose substantially pure population of viable (cultured) pancreatic progenitor cells (cultured cell lines: RIN1027-B2 and RIN1046-38), which

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express PDX-1 (same as IDX-1) and resemble islet β -cells and islet δ cells. A subset of the differentiated pancreatic progenitor cells (RIN-1046-38) expresses and secretes (produces) insulin ((see column 7, lines 44-51 and column 10, lines 10-47). PDX-1 is known to be involved in pancreatic development in neonates and is expressed in fetal pancreas ontogeny (see column 9, lines 21-28). PDX-1 is known to be a marker for β and δ cell lineages in pancreatic progenitor islet cells of adults (see column 11, lines 17-23 and column 22, lines 3-46).

In as far as the limitation that the pancreatic progenitor cells are “able to differentiate into glucose-responsive cells”, the recitation of “able to differentiate” is not a positive limitation of the claim; therefore, the viable pancreatic progenitor cells in the claimed invention are not required to differentiate into glucose-responsive cells.

Alternatively, since the viable pancreatic progenitor cells are recited to be characterized by expression of PDX-1 which renders them capable of differentiating into glucose-responsive and insulin-secreting cells, and Habener specifically taught that cell line RIN1046-38 are β -cell lineage pancreatic progenitor cells which express PDX-1 and produce or secrete insulin, it is determined that Habener inherently anticipates the claimed invention because production or secretion of insulin of the RIN1046-38 cells is a result effected by a response of the same cells to the presence or increase in glucose levels. Hence, the viable pancreatic progenitor cells of Habener are deemed to be glucose-responsive cells.

6. No claims are allowed.

Remarks

7. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Egan et al. (US Patent 7,056,734) which post-dates the instant application's date of priority disclose a method of making a substantially pure population of insulin secreting cells which express PDX-1 (IDX-1). According to Egan et al., PDX-1 expression is required for insulin secretion from a cell (see column 10, lines 4-13)

Fung et al. (US Patent 6,326,201) which post-dates the instant application's date of priority disclose substantially pure population of viable pancreatic progenitor cells that express PDX-1, and differentiate into glucose-responsive and insulin expressing and secreting cells (see Summary).

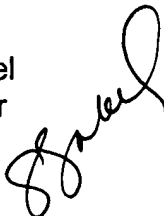
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gailene R. Gabel
Patent Examiner
Art Unit 1641
July 26, 2006

A handwritten signature in black ink, appearing to read 'Gabel', is written over the printed name and date.